REMARKS/ARGUMENTS

Claims 1-5, 7-10 and 31-62 are pending. By this amendment, claims 1, 5, 8 and 32 are amended and new claims 59-62 are added.

The Office Action rejects claims 5, 8, 32-37 under 35 U.S.C. § 112, second paragraph. Claims 5, 8 and 32 have been amended and obviate this rejection. Withdrawal of the rejection is requested.

The Office Action rejects claims 1-5, 10, 31-33, 35-37, 47, 50, 52, 53, 56, and 58[1] under 35 U.S.C. § 102(b) over Hansen (U.S. Patent No. 6,357,440). This rejection is respectfully traversed.

Claims 1 and 32 recite that "the covering portion is inflated under the influence of the respiratory gas in use." Independent claim 46 recites "the front portion consisting essentially of a flexible portion of material which is inflated under the influence of the pressurized gas in use." These features are not disclosed or suggested in Hansen. In contrast, Hansen discloses mask shell 104 and an impermeable coating 115 extending over portions of the mask shell 104. The impermeable coating 115 extends over predetermined areas of the mask shell 104, and reduces the available venting areas of the mask shell 104, in exchange for rigidity in the mask 100. Vent portions 119 are left between the areas where the impermeable coating 115 is applied. As may be seen in Fig. 2, the impermeable coating 115 covers a majority of the mask shell 104. See col. 2, lines 9-55.

Hansen does not disclose or suggest that the mask shell 104 will inflate under the influence of pressurized gas, and instead specifically discloses that the impermeable coating 115 is applied to provide rigidity to the mask shell 104. Regarding claims 46, the Office Action asserts that the gas outflow area 119 provides diffuse outflow of gas, and that the covering portion would inherently inflate when a gas is delivered to the interior of the mask due to its flexibility. This assertion is respectfully traversed.

Hansen utilizes an impermeable coating 115 over a majority of the mask shell 104, to provide rigidity to the mask shell 104. However, inherency requires that the characteristic

[1] The Office Action apparently intended to include claim 46 in this rejection, since it is discussed in this section of the Office Action, and it will so be treated herein.

necessarily is present in the prior art reference. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). A flexible material stretched between and/or supported by an element or elements present to provide rigidity will not necessarily inflate under the influence of pressurized gas, as would be required for a showing of inherency. For example, a material can have varying degrees of flexibility, where the material may not inflate at all, especially while supported by a more rigid element or elements.

For the above reasons, it is submitted that claims 1, 32 and 46, and all claims dependent therefrom, are not anticipated by Hansen. Withdrawal of the rejection is requested.

The Office Action rejects claim 8 under 35 U.S.C. § 103(a) over Hansen, rejects claim 9 under 35 U.S.C. § 103(a) over Hansen in view of Schwarz (U.S. Patent No. 2,931,356), rejects claim 49 under 35 U.S.C. § 103 (a) over Hansen in view of Aspelin (U.S. Patent No. 3,971,369), and rejects claim 51 under 35 U.S.C. § 103 (a) over Hansen in view of Bulmer (U.S. Patent No. 1,878,464). These rejections are respectfully traversed.

Claims 8, 9, 49 and 51 are not obvious at least because of the above-noted deficiencies regarding claims 1 and 46, from which claims 8, 9, 49 and 51 depend. Withdrawal of the rejections is requested.

Further, regarding claims 49 and 51, Aspelin is directed to non-analogous art. In particular, claims 49 and 51 are directed to a respiratory mask for delivering breathable gas to a patient at a level that is above ambient pressure. The mask includes a mask body having a front portion consisting essentially of a flexible portion of material that is inflated under the influence of pressurized gas in use (as recited in independent claim 46). In contrast, Aspelin is not in the same field of endeavor (respiratory masks that receive pressurized gas in use), but is instead merely a disposable fold flat respirator mask that does not receive pressurized gas. Even if Aspelin was from the same field of endeavor, which it is not, Aspelin is not concerned with the problem addressed by the claims 49 and 51, namely providing a gas outflow area in a pressurized respiratory mask that enables a diffuse outflow of gas while emitting little noise, and inflates under the influence of the pressurized gas that is at a level above ambient pressure. Instead, in

Aspelin, the mask is acting as a filter medium, with the entire front of the mask filtering bacteria. See col. 4, lines 39-46, for example. Accordingly, Aspelin is directed to non-analogous art. Moreover, it is submitted that one of ordinary skill in the art would not have combined Aspelin with Hansen as suggested. The Office Action asserts that the perforations of Aspelin would allow one to precisely control the flow through the film. However, Hansen already includes vent portions with a permeable material that allows precise control of the flow through the material based on the material selected, such as the woven fabric. Accordingly, one of ordinary skill in the art would not have been motivated to include perforations in addition to the permeable woven material. For the above reasons, it is submitted that claims 49 and 51 would not have been obvious over Hansen in view of Aspelin. Withdrawal of the rejections is requested.

The Office Action rejects claims 7, 34, 48, 54 and 56 under 35 U.S.C. § 103(a) over Hansen in view of Griesbach (U.S. Patent No. 6,948,499). This rejection is respectfully traversed.

Claims 7, 34 and 48 are not obvious over Hansen in view of Griesbach at least because these claims depend from claims 1, 32 or 46, and because Griesbach does not solve the above-noted deficiencies of Hansen. Claim 54 (and dependent claim 56) include the recitation of "the front portion consisting essentially of a flexible portion of GORE-TEX® material which is inflated under the influence of the pressurized gas in use." The transitional phrase "consisting essentially of" limits the scope of the front portion to a flexible portion of GORE-TEX® material which is inflated under the influence of the pressurized gas in use. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

Even if the woven material of Hansen was substituted with the PTFE membrane of Griesbach, the combination would still include the front portion having the impermeable coating to provide rigidity, which would materially affect the basic and novel aspect of the claim 54 mask, as such rigidity would prevent inflation of the front portion of the mask under the influence of the pressurized gas in use. Therefore, the asserted combination would not result in "the front portion consisting essentially of a flexible portion of GORE-TEX® material which is inflated under the influence of the pressurized gas in use," as recited in claim 54.

Further, Griesbach is directed to non-analogous art. In particular, the claims are directed to a respiratory mask that that is inflated under the influence of respiratory or pressurized gas in use. In contrast, Griesbach is not in the same field of endeavor (respiratory masks that receive respiratory or pressurized gas in use), but is instead merely a disposable respirator mask that does not receive respiratory or pressurized gas. Even if Griesbach was from the same field of endeavor, which it is not, Griesbach is not concerned with the problem addressed by the claims 54 and 56 inventions, namely providing a gas outflow area in a pressurized or respiratory mask that enables a diffuse outflow of gas while emitting little noise, and inflates under the influence of the respiratory or pressurized gas. Instead, in Griesbach, the mask is acting as a filter medium, with the entire front of the mask filtering pathogens from the exhaled air. See col. 2, lines 5-25, for example. Accordingly, Griesbach is directed to non-analogous art.

Moreover, it is submitted that one of ordinary skill in the art would not have combined Griesbach with Hansen as suggested. The Office Action asserts that the PTFE of Griesbach would provide better filtration than the woven material of Griesbach. However, Hansen is not a surgical mask that needs filtration of pathogens from exhaled air. Accordingly, one of ordinary skill in the art would not have been motivated to add the PTFE of Griesbach to the mask of Hansen. For the above reasons, it is submitted that claims 7, 34, 48, 54 and 56 would not have been obvious over Hansen in view of Griesbach. Withdrawal of the rejections is requested.

The Office Action rejects claim 55 under 35 U.S.C. § 103(a) over Hansen in view of Griesbach further in view of Bulmer (U.S. Patent No. 1,878,464), and rejects claims 57 under 35 U.S.C. § 103(a) over Hansen in view of Griesbach and further in view of Aspelin (U.S. Patent No. 3,971,369). These rejections are respectfully traversed.

Claims 55 and 57 would not have been obvious over the applied references at least because of their dependence from claim 54, and because Aspelin, Griesbach and Bulmer do not solve the above-noted deficiencies of Hansen regarding claim 54. Withdrawal of the rejections is requested.

The Office Action rejects claims 38, 40-42 and 45 under 35 U.S.C. § 103(a) over Hansen in view of Maryyanek (U.S. Patent No. 4,600,002). This rejection is respectfully traversed.

Claim 38 recites "the front portion comprising a flexible portion of material which is inflated under the influence of the pressurized gas in use." As noted above, Hansen does not

disclose or suggest the front portion of the mask is inflated under the influence of the pressurized gas in use as recited in claim 38. Maryyanek does not solve this deficiency.

Further, claim 38 recites the flexible portion of material includes at least one stitched seam segment, the at least one stitched seam segment and a shape of the flexible portion of material being configured and arranged to provide a defined shape upon supply of the pressurized gas to the mask interior. Maryyanek does not disclose or suggest the at least one stitched seam segment and a shape of the flexible portion of material being configured and arranged to provide a defined shape upon supply of the pressurized gas to the mask interior, especially considering that the mask of Maryyanek does not utilize pressurized gas, and thus it's stitched seam cannot be configured to provide a defined shape upon supply of the pressurized gas to the mask interior. Further, because the mask of Hansen does not disclose inflating, even if combined as suggested, the resulting combination will not have this feature of claim 38. There is no evidence that would lead to the conclusion that one of ordinary skill in the art could have achieved a predictable result when considering whether to apply the Maryyanek stitch to the Hansen mask. In particular, there is no disclosure in Maryyanek or Hansen that utilizing the stitched seam of Maryyanek in the mask of Hansen would lead to a predicatable result of a providing a defined shape upon supply of a pressurized gas to a mask interior, especially when considering that Hansen utilizes an impermeable coating over a majority of the mask shell, to provide rigidity to the mask shell, which will provide a defined shape in the absence or with application of pressurized gas. Maryyanek does not utilize pressurized gas, and as such provides no predictability that utilization of the stitched seam will somehow provide a defined shape upon supply of pressurized gas to a mask interior.

Further, Maryyanek is directed to non-analogous art. In particular, claim 38 is directed to a respiratory mask having a front portion, the front portion comprising a flexible portion of material which is inflated under the influence of the pressurized gas in use. In contrast, Maryyanek is not in the same field of endeavor (respiratory masks that receive pressurized gas in use), but is instead merely a disposable fold flat respirator mask that does not receive pressurized gas. Instead, Maryyanek uses layered air filtering and absorbing materials to protect a user from toxic gases or vapors. See col. 2, lines 32-45, for example. Even if Maryyanek was from the same field of endeavor, which it is not, Maryyanek is not concerned with the problem addressed

by the claim 38 invention, namely providing a gas outflow area in a pressurized respiratory mask that enables a diffuse outflow of gas while emitting little noise, and inflates under the influence of the pressurized gas. Instead, in Maryyanek, the mask is acting as a filter medium, with the entire front of the mask filtering toxic gases or vapors. Accordingly, Maryyanek is directed to non-analogous art.

Moreover, it is submitted that one of ordinary skill in the art would not have combined Maryyanek with Hansen as suggested. The Office Action asserts it would have been obvious to provide the stitched seam of Maryyanek to the mask of Hansen to provide the mask of Hansen with a shape that promotes a better seal. However, in Maryyanek, the respirator is formed from right and left webs of layered air-filtering and absorbing materials joined together at vertical seam 25, where the webs are die cut to shape with cut-out contoured edges 28 and 30. See col. 2, lines 32-47. Hansen does not include such right and left webs that are die cut to shape with cut-out contoured edges, needing to be joined together with a stitched seam. Further, the Office Action fails to consider that such a stitched seam could adversely affect the sealing ability of the Hansen mask, a problem not present in the Maryyanek disposable fold flat respirator mask that does not receive pressurized gas. As such, one of skill in the art would not have been motivated to make the suggested combination. Withdrawal of the rejections is requested.

For the above reasons, it is submitted that claim 38, and dependent claims 40-42 and 45 would not have been obvious over Hansen in view of Maryyanek. Withdrawal of the rejection is requested.

The Office Action rejects claim 39 under 35 U.S.C. § 103 (a) over Hansen in view of Maryyanek and further in view of Aspelin, rejects claims 43 under 35 U.S.C. § 103(a) over Hansen in view of Maryyanek and further in view of Griesbach, and rejects claim 44 under 35 U.S.C. § 103(a) over Hansen in view of Maryyanek and further in view of Bulmer. These rejections are respectfully traversed.

Claims 39, 43 and 44 would not have been obvious over the applied references at least because of their dependence from claim 38, and because Maryyanek, Aspelin, Griesbach and Bulmer do not solve the above-noted deficiencies of Hansen regarding claim 38. Withdrawal of the rejections is requested.

New claim 59 recites "the at least one stitched seam segment comprises a plurality of stitched seam segments," new claim 60 recites "the plurality of stitched seam segments comprise a plurality of vertical stitched seam segments," new claims 61 recites "a plurality of woven material zones are defined between the plurality of stitched seam segments" and new claim 62 recites "the course of the stitched seam segments and a shape of the woven material zones are adapted to provide the defined shape upon supply of the pressurized gas to the mask interior." These features are not disclosed in the applied references.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been fled herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4750-34.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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